

## **HEADACHE RELIEF ADDED STRENGTH- acetaminophen, aspirin and caffeine tablet, film coated**

**Publix Super Markets Inc**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Publix Super Markets, Inc. Headache Relief Drug Facts**

#### **Active ingredient (in each tablet)**

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)\*

Caffeine 65 mg

\*nonsteroidal anti-inflammatory drug

#### **Purpose**

Pain reliever

Pain reliever aid

#### **Uses**

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- sinusitis
- arthritis
- a cold
- toothache
- premenstrual and menstrual cramps

#### **Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 tablets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach

bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

### **When using this product**

the recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heart beat.

### **Do not use**

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- if you are allergic to aspirin
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

### **Ask a doctor before use if**

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

### **Ask a doctor or pharmacist before use if you are**

taking a prescription drug for

- diabetes
- gout
- arthritis

### **Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
  - redness or swelling is present
  - any new symptoms occur
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- ringing in the ears or a loss of hearing occurs

These could be signs of a serious condition

### **If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin during the last 3 months

of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- do not use more than directed (see Liver warning)
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 tablets every 6 hours; do not exceed 8 tablets in 24 hours
- children under 12 years: ask a doctor

**Other information**

store at 20°-25°C (68°-77°F)

**Inactive ingredients**

carnauba wax, crospovidone, FD&C blue no. 1 lake, hypromellose, microcrystalline cellulose\*\*, povidone, propylene glycol, saccharin sodium, starch, stearic acid, titanium dioxide \*\*may contain this ingredient

**Principal Display Panel**

SEE NEW WARNINGS INFORMATION

ADDED STRENGTH

headache relief

ACETAMINOPHEN, ASPIRIN (NSAID) & CAFFEINE

PAIN RELIEVER/PAIN RELIEVER AID

headaches

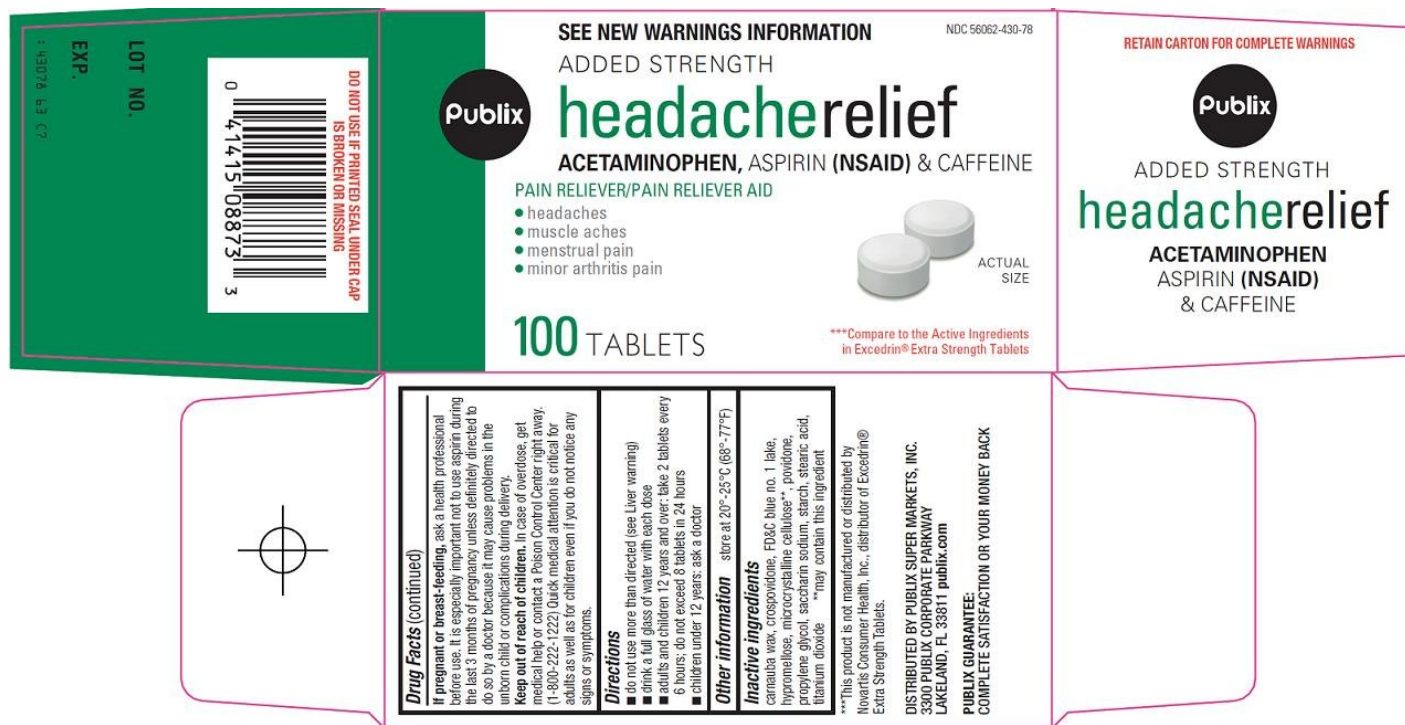
muscle aches

menstrual pain

minor arthritis pain

ACTUAL SIZE

Compare to the Active Ingredients in Excedrin® Extra Strength Tablets



Headache Relief Carton Image 1

## Drug Facts

### Active ingredients (in each tablet) Purpose

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Aspirin 250 mg (NSAID)*.....	Pain reliever
Caffeine 65 mg.....	Pain reliever aid
*nonsteroidal anti-inflammatory drug	

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■ headache ■ muscular aches ■ sinusitis  
■ arthritis ■ a cold ■ toothache  
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## Drug Facts (continued)

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- if you are allergic to aspirin
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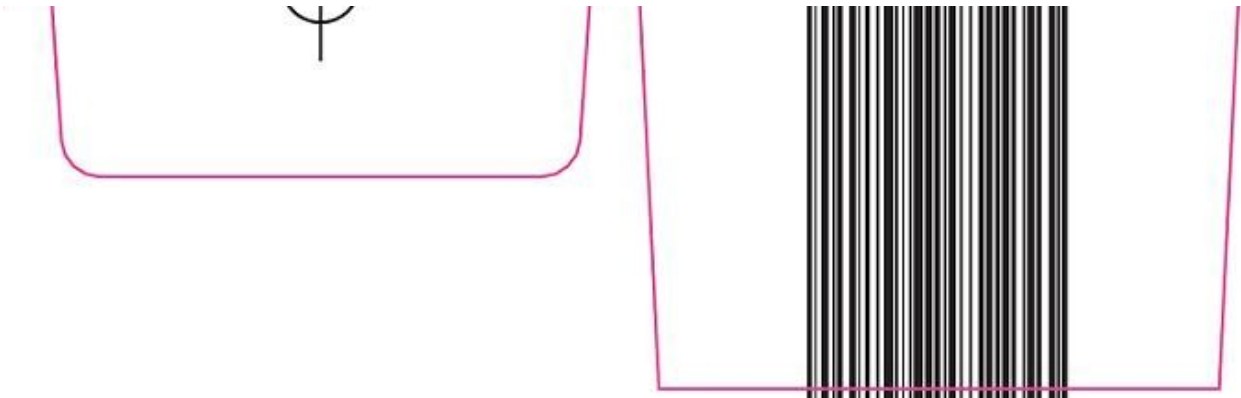
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Headache Relief Carton Image 2

HEADACHE RELIEF   ADDED STRENGTH

acetaminophen, aspirin, caffeine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-430
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPOLYMER (UNII: 68401960MK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYVINYL PIPERIDINE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	L430
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-430-78	1 in 1 CARTON		
1		100 in 1 BOTTLE		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part343	08/24/1998	

**Labeler** - Publix Super Markets Inc (006922009)